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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
HELMER, GEORGIA L	

ART UNIT	PAPER NUMBER
1638	

DATE MAILED: 10/22/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/724,726	HADLACZKY ET AL.	
	Examiner	Art Unit	
	Georgia L. Helmer	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 July 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *50-52* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *50-52* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Status of the Claims

1. The Office acknowledges receipt of Applicants Response; dated 16 July 2003.

2. Applicant has amended claim 50. Claims 50-52 are pending and are examined in this Office Action.

3. Applicant traverses the restriction requirement of November 1, 2002, which has been made Final. If Applicant wishes to further protest this restriction requirement, Applicant may petition under 37 CFR 1.181 (MPEP 818.03(c)).

4. The Office acknowledges receipt of the Declaration of Steven Fabijanski, PhD, dated 16 July 2003.

5. All rejections not recited below have been withdrawn.

6. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112-second

7. Claims 50-52 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "satellite artificial chromosome" is unclear. What is a satellite artificial chromosome?

Applicant recites various qualities of an satellite artificial chromosome:

- it contains "satellite DNA" (specification, p. 5). What is "satellite DNA" and how does it differ from other DNA?
- it is a "fully functional stable chromosome" (specification, p. 5).
- it provides an extra genomic locus for targeted integration of DNA (specification, p. 5).
- it is primarily made up of "repeating units of short satellite DNA" and are "nearly fully heterochromatic" (specification, p. 7). What does "nearly fully" mean? 50%? 90%?

However a recitation of properties of a satellite artificial chromosome does not teach what the essential elements of satellite artificial chromosome are, nor does this make the metes and bounds of satellite artificial chromosome apparent.

Applicant traverses, stating primarily (Response, p.7) that methods of introducing SATAC into plant cells are provided in great detail throughtout the specification.

Applicant's traversal has been considered and is unpersuasive. Applicant refers only to animal cells and animal SATAC. Lacking is any teaching of what the essential components of a SATAC are, or of plant SATAC into plant cells.

The art of DNA introduction into plant cells and tissues in general is known. *Relevant variables for any given situation of use in this process are the specific plant(s), and the nature and size of the DNA, including the replicon used, among other things.*

Claim Rejections - 35 USC § 112 Written Description

8. Claims 50-52 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claimed invention lacks written description under current written description guidelines. The claims are drawn to a method of producing a transgenic plant comprising introducing a SATAC into a plant protoplast, and growing the protoplast under conditions to produce a transgenic plant, also to the method where the SATAC comprises a heterologous DNA that encodes a gene product, and to the method where the SATAC is introduced by cell fusion, lipid mediated transfection, microinjection, microcell fusion, electroporation, microprojectile bombardment, nuclear transfer or direct DNA transfer.

Applicant should note that insufficient identifying characteristics are set forth for the satellite artificial chromosome or the plant SATAC. If the claimed satellite artificial chromosome itself cannot be identified by characteristics clearly disclosed in the specification, then it is not even possible to determine whether a method using a satellite artificial chromosome is or is not covered by the claim. Thus, satellite artificial

chromosomes and plant artificial chromosomes that are not disclosed in sufficient identifying characteristics are not considered to be possessed by Applicant. There is insufficient relevant identifying characteristics to allow one skilled in the art to predictably determine the structure and function of a satellite artificial chromosome in order to use the satellite artificial chromosome as starting material for a method of producing a cell that contains heterologous nucleic acid or to identify a cell containing a satellite artificial chromosome or a plant satellite artificial chromosome.

See *University of California v. Eli Lilly*, 119 F.3d 1559, 43 USPQ 2d 1398 (Fed, Cir. 1997), where it states: "The name cDNA is not in itself a written description of that DNA; it conveys no distinguishing information concerning its identity. While the example provides a process for obtaining human insulin-encoding cDNA, there is no further information in the patent pertaining to that cDNA's relevant structural or physical characteristics; in other words, it thus does not describe human insulin cDNA . . . Accordingly, the specification does not provide a written description of the invention . . ."

Accordingly, there is a lack of adequate written description for the claimed methods, for satellite artificial chromosomes, and for plant satellite artificial chromosomes , and in view of the level of knowledge and skill in the art, one skilled in the art would not recognize from the disclosure that Applicant was in possession of the claimed invention at the time of filing. Accordingly, the claimed invention lacks adequate written description under current written description guidelines. (See, Written Description Examination Guidelines (published in Federal Registry/Vol. 66, No.4/Friday, January 5, 2001/Notices: p. 1099-1111).

Claim Rejections - 35 USC § 112.1 Enablement

9. Claims 50-52 remain rejected under 35 U.S.C. 112, first paragraph, because the claimed invention lacks written description, as discussed above. Since the claimed invention lacks written description, one skilled in the art would not know how to make or use the claimed invention.

10. Claims 50-52 remain rejected under 35 U.S.C. 112, first paragraph, for reasons of record. See Office Action 17 January 2003:

> [T]he specification, while being enabling for a mammalian SATAC in a mammalian cell, does not reasonably provide enablement for any SATAC in any cells. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.
>
> Applicant's invention relates to methods for preparing cell lines containing artificial chromosomes, methods of isolating artificial chromosomes and methods for delivery of artificial chromosomes to selected cells and tissues.
>
> Applicant discloses an animal SATAC. Applicant's claims are drawn to any SATAC. Mammals, and animals, are not representative of plants in terms of chromosomes and chromatin structure. In animals and in yeast, satellite DNA is AT-rich, whereas plant satellite DNA tends to be GC-rich (Ferl, R et al in Buchanan, et al. Biochemistry & Molecular Biology of Plants (2000) American Society of Plant Physiologists, Rockville Md 20855, page 324.) GC-rich DNA differs in physical properties from AT-rich DNA; GC rich DNA is more compact and dense, reflecting its more highly hydrogen-bonded structure (Lehninger, A. Biochemistry. 2nd edition, 1976, Worth Publishers, New York. p 864). It is unclear how compact, densely H-bonded DNA affects SATAC activity and function. Furthermore, telomeres, origin of DNA replication and a centromere are required for function of a SATAC (Willard, HF, Science, 290, pps 1308-9, 2000). It is unclear what telomeres, origin of DNA replication and centromere are necessary for other than animal SATACs, whether additional components are required, or how to isolate or construct functional SATAC in all cells, or non-mammalian cells. Plant centromeres have yet to be physically constructed or isolated. However, plant centromeres of Arabidopsis have been defined by genetic and sequence analysis (Copenhaver, et al, Science, 286, December, 1999, pages 2468-2474). Centromeres of artificial chromosomes appear to show some species-specific behavior in animal systems (Willard, HF, Science, 290, pps 1308-9, 2000; Shen, et al, Current Biology 10, 31-34, 2000; Telenius, et al, Chromosome Research 7, pages 3-7, 1999; Ferl, R et al in Buchanan, et al. Biochemistry & Molecular Biology of Plants (2000) American Society of Plant Physiologists, Rockville Md 20855, page 324,5). It is unpredictable that plants, from a totally different Kingdom than animals, would have centromeres which are

structurally and biochemically the same as those of animals. Neither the Applicant, nor the prior art, teaches how to isolate or make plant centromeres, nor how to make a SATAC having a plant centromere. Rather it is predictable that plant centromeres would differ from animal centromeres, since animal centromeres differ among themselves and show species-specific behavior. Patterns of heterochromatin differ between animal and plants, with animals showing heterochromatization in telomeres, centromeric, and pericentrometic regions. In plants, however, heterochromatin is located at the nucleolar organizer, and at the chromosome knobs. See Avramova, Plant Physiology, 2002, vol 129, pages 40-49. Plant heterochromatin differs from animal heterochromatin in the absence of proteins similar to known heterochromatin proteins, location of potentially active genes in the knob structures and in the periocentromeric regions of plant genome, and different chromosomal environments for collinear genes in related species (Avramova, op cit, p 41). In fact plants have a family of 20 methyltransferase enzymes unique to plants, putatively representing host factors necessary for proper function of plant systems and not required in other systems. Therefore, given that plant satellite DNA, plant centromeres and plant heterochromatin differ from their animal counterparts, it is unpredictable that a plant SATAC, consisting of those components, would function as desired in the claimed invention.

Simple heterologous expression constructs in animal host systems are clearly structurally different from heterologous expression constructs in other host systems, including plants. Required are different promoters, enhancers, codon optimization, termination regions, and other regulatory regions. One of skill in the art would expect a SATAC constructed for mammalian cells to differ from a SATAC functional in a non-mammalian cell. SATACs are much more complex, than just the mere heterologous expression system, and require manipulation of much larger size DNA. The transfer of large pieces of DNA between cells in a major problem in artificial chromosome technology (Brown, Trends in Biotech, 2000, vol 18, p 403; Perez, et al, Trends in Biotech, 2000, 18, 402-3; Willard, HF, Science, 290, 1308-9, 2000; Hadlaczky, Curr. Opin. Mol Ther, 2001, vol 3, pages 125-32, p 129).

It is unclear what regions of Applicant's animal SATAC should be retained, and what regions should be modified, to obtain a SATAC that would be operable in a non-mammalian cell. The art of artificial chromosome technology is in its infancy (Willard, HF, Science, 290, pps 1308-9, 2000, final paragraph). Therefore, much greater guidance would be required. Applicant teaches an animal SATAC in a mammalian cell. Applicant does not address any of the issues set forth above. While one skilled in the art can readily make necessary changes to Applicant's mammalian SATAC to generate a non-mammalian SATAC, guidance is required as to what those changes are. To require one skilled in the art to randomly make changes to Applicant's animal SATAC, or to generate their own SATAC constructs without guidance as to how inoperable embodiments can be readily eliminated other than by trial and error, is an invitation to experiment, requiring excessive and undue experimentation. Accordingly Applicant has not sufficiently enabled a SATAC generated from any source as commensurate in scope with the claims.

> Applicant discloses human, mouse, and hamster cells. The claims are drawn to any cell, including, any non-mammalian animal, any plant, any yeast and any bacteria. While mammalian and nonmammalian cells have been extensively used to express heterologous constructs, the constructs much be recognized by the cell machinery. Otherwise, the construct would be degraded or removed from the cell. No construct to date is universally recognized in all cells. One skilled in the art would expect that a SATAC construct for a mammalian cell would also differ from a SATAC construct for a bacteria cell, a yeast, cell, a insect cell, and a plant cell.
>
> Applicant does not disclose that the SATAC of the instant application is universally adapted to be operable in all cell types. Applicant has only shown that Applicant's SATAC is operable in a mammalian cell. It is unpredictable that Applicant's SATAC would be operable in all cell types. Accordingly, Applicant has only enables Applicant's SATAC for a mammalian cell. Thus Applicant is not enabled for using an SATAC in any cell type, as commensurate in scope with the claims.

Applicant traverses, stating primarily (Response, p.11) that reliance on post-filing date references to establish a lack of enablement is improper.

Applicant's traversal has been considered and is unpersuasive. While the MPEP states

> In general, the examiner should not use post-filing date references to demonstrate that the patent is non-enabling.

The remainer of the MPEP paragraph is:

> Exceptions to this rule could occur if a later-dated reference provides evidence of what one skilled in the art would have known on or before the effective filing date of the patent application. In re Hogan, 559 F.2d 595, 605, 194 USPQ 527, 537 (CCPA 1977). If individuals of skill in the art state that a particular invention is not possible years after the filing date, that would be evidence that the disclosed invention was not possible at the time of filing and should be considered. In re Wright, 999 F.2d 1557, 1562, 27 USPQ2d 1510, 1513-14 (Fed. Cir. 1993) an article published 5 years after the filing date of the application adequately supported the examiner's position that the physiological activity of certain viruses was sufficiently unpredictable so that a person skilled in the art would not have believed that the success with one virus and one animal could be extrapolated successfully to all viruses with all living organisms. Claims not directed to the specific virus and the specific animal was held nonenabled. MPEP 2164.04(R-1)

The cited reference (Willard, 2000) is by an individual of skill in the art stating that the disclosed and claimed invention is not possible years after the filing date, and this is evidence that the disclosed invention was not possible at the time of filing. Thus the citation and application of Willard to establish lack of enablement fits the above exception and is proper.

11. Applicant traverses, stating primarily (Response, p.11-12) that "one does not have to know what components are required or what telomeres are needed or other parameters" in order to produce a satellite artificial chromosome, that knowledge of the mechanism is not needed. Applicant further traverses that the amplification event that leads to generation of satellite artificial chromosomes does occur in plants, citing US 6,355,860 and 6,100,092.

Applicant's traversal has been considered and is unpersuasive because the patent application must be enabled as of the date of filing. US 6,355,860 and 6,100,092 issued 12 March 2000 and 8 August 2002, respectively. Applicant's priority date appears to be 10 April 1996. Therefore the post-filing date references cannot be used to support enablement as of the date of filing. Further, the Office does not understand how one could produce a SATAC if one did not know what components are required. How does one know one has a SATAC?

12. Applicant traverses, stating primarily that (Response, p.12) from case law, that it is manifestly impractible for an Applicant who discloses a generic invention to give an example of every species falling within it, ...".

Applicant's traversal has been considered and is unpersuasive because the specification is lacking any exemplification of even a single species of a plant satellite artificial chromosome. Applicant allegedly teaches mammalian satellite artificial chromosomes. Animals and plants are in totally different biological groups; animals and plants are in different Kingdoms phylogenetically (Raven et. al., Botany, 1992, Worth Publishers, NY, NY 10003, pages 171-185). The Office presumes that a plant satellite artificial chromosome is made of identifiably plant components. However, no identifiable components of a SATAC are taught, as discussed above.

13. Applicant traverses, stating primarily that (Response, p.14) the level of knowledge and skill in the construction, introduction into cells and stable expression of large sizes of DNA was so high as of the effective filing date that it would not have required extensive experimentation by one of ordinary skill in the art to produce plant satellite artificial chromosome by the method in the working examples and publication incorporated, nor would it have required extensive experimentation to transfer the resulting plant artificial satellite artificial chromosome into a plant cell.

Applicant's traversal has been considered and is unpersuasive. This argument presents a conclusory statement without evidentiary support. The Office does not contest that once one has a plant SATAC, transformation of plant cells was within the skill of the art. However, production of a plant SATAC is not within the skill in the art.

No evidence for the production of a plant SATAC is given. The Fabijanski Declaration is lacking any showing of a plant SATAC, as discussed below. Without the plant SATAC, one could not practice the claimed method.

14. Applicant traverses, stating primarily that (Response p. 14) the specification describes methods for generation and identification of satellite artificial chromosomes, and provides a broad disclosure that can be practiced with any eukaryotic cell. Applicant asserts that it is only necessary to introduce a piece of DNA and a selectable marker into a cell, grow the cell under selective conditions, look for cells that contain satellite artificial chromosome, and select such cells and isolate a satellite artificial chromosome therefrom.

Applicant's traversal has been considered and is unpersuasive because use of a selectable marker is not part of the claimed method. Rather, without knowing precisely what plant SATACs look like, it is not possible to screen for cells that contain a plant SATAC.

15. Applicant traverses, stating primarily (Response, p.14) that there is no evidence of record to suggest that such events (generation of satellite artificial chromosomes) are unique to animal cells, nor is there any reason to believe such.

Applicant's traversal has been considered and is unpersuasive because the art of record (see January 2003 Office Action, p. 10) clearly differentiates the DNA structure and function of animal satellite DNA compared to plant satellite DNA. While plant

SATACs may exist, Applicant has failed to sufficiently describe them such that one skilled in the art could make them.

16. Applicant traverses, stating primarily (Response, p. 15) that generation of a satellite artificial chromosome requires an amplification event and there is no reason provided by the Examiner that suggest that plant chromosomes do not undergo amplification, and that plants do have amplifiable regions, citing US 6,355,860 and 6,100,092 issued 12 March 2000 and 8 August 2002, respectively.

Applicant's traversal has been considered and is unpersuasive because Applicant's priority date appears to be 10 April 1996, which predates the cited patents, and the disclosure must be enabled as of the date of filing. Moreover, even if plant amplifiable regions were known at the time of filing, this knowledge would not lead one to make plant SATACs. Again, one needs to know what a plant SATAC is before one can make it.

17. Applicant traverses, stating primarily (Response, p. 24) that the specification describes the production , characterization and isolation of satellite artificial chromosomes and their transfection into cells. Applicant asserts that the specification provides numerous working examples of the procedures and results involved in the claimed methods.

Applicant's traversal has been considered and is unpersuasive because all the examples set forth are of animal DNA, and of animal cells. Animals and plants are in totally different biological groups; animals and plants are in different Kingdoms

phylogenetically. Animals are multicellular organisms having no cell walls, lack photosynthetic apparatus and therefore are heterotrophic, i.e. unable to produce their own food, and possess contractile fibers which allow them to move. Plants are multicellular organisms having cellulosidic cells wall, photosynthetic apparatus and therefore are auxotrophic, and generally lack the ability to move themselves. (Raven et. al., Botany, 1992, Worth Publishers, NY, NY 10003, pages 171-185). Animal DNA different from plant DNA in that plant DNA has a higher concentration of GC base pairs that does animal DNA, making the plant DNA physically more dense and packed closer together. Whereas animal DNA, have a lower GC base pair content, has DNA which is physically less dense and less densely packed together. Also plant satellite DNA is higher in GC content than is animal DNA, again suggesting that plant DNA and animal DNA have different physical and biochemical characteristics (Lehninger, op. cit.)

18. Applicant traverses, stating primarily (Response, p.16) that Applicant provides to the public no less than six of the described cells lines that have been deposited at an authorized depository.

Applicant's traversal has been considered and is unpersuasive because all of these cell lines are mammalian cell lines. Animals and plants are in totally different biological groups; animals and plants are in different Kingdoms phylogenetically (Raven et. al., Botany, 1992, Worth Publishers, NY, NY 10003, pages 171-185).

19. Applicant traverses, stating primarily (Response, p18) that the specification describes how to introduce satellite artificial chromosomes into plant cells using direct DNA transfer methods.

Applicant's traversal has been considered and is unpersuasive because no examples are set forth for methods of introducing intact DNA of large sizes into plant cells.

20. Applicant traverses, stating primarily (p. 24) that the specification provides numerous working examples and description of the construction, isolation and transfer of satellite artificial chromosomes from various sources such as plant systems, into various cells, such as plant cell.

Applicant's traversal has been considered and is unpersuasive because all the working examples are of animal cells and animal satellite artificial chromosomes. Applicant has not given a single working example of a plant satellite artificial chromosome or a plant satellite artificial chromosome in a plant cell.

21. Applicant traverses, stating primarily (p. 27) that the Office Action does not provide suggestions based in the art that the composition of satellite DNA is linked to function. That the mere fact that GC-rich DNA is more densely packed than AT-rich DNA should not effect the structure or function of a satellite artificial chromosome, which is already formed from a high percentage of densely packed heterochromatin.

Applicant's traversal has been considered and is unpersuasive because Examiner has cited references describing plant satellite DNA, and related this plant satellite DNA structure to function. The satellite DNA structure of plants and animals do differ, as reiterated below:

> In animals and in yeast, satellite DNA is AT-rich, whereas plant satellite DNA tends to be GC-rich (Ferl, R et al in Buchanan, et al. Biochemistry & Molecular Biology of Plants (2000) American Society of Plant Physiologists, Rockville Md 20855, page 324.) GC-rich DNA differs in physical properties from AT-rich DNA;

> GC rich DNA is more compact and dense, reflecting its more highly hydrogen-bonded structure (Lehninger, A. Biochemistry. 2nd edition, 1976, Worth Publishers, New York. p 864).

22. Applicant traverses, stating primarily (Response p. 16) that the specification provides a method for generating species specific satellite artificial chromosomes by adding a centromere from other species, and that references cited by Applicant (p. 16-18) provide a means to identify and isolate plant centromere DNA sequences.

Applicant's traversal has been considered and is unpersuasive because the recited references do not describe or provide an isolated plant centromere. Applicant traverses, stating primarily that (Response, p.26) references cited by the Examiner (Shen et. al. and Telenius et. al.) show that artificial chromosomes can be transferred between a wide variety of cells . Therefore, the species variation of centromere sequence, if any, has no bearing on the predictability of the methods as instantly claimed. Applicant's traversal has been considered and is unpersuasive because the cited references do not support the predictability of the art; rather ***they support the unpredictability*** of the art. The cited references set forth examples of systems operable in animals, and in animals only. No teaching of Plants or plant systems, or of any other Kingdom than Animals is given. Examiner 's references properly ***support the unpredictability*** of the art.

23. Applicant traverses, stating primarily (Response, p. 36) that there is precedence in the art that a satellite artificial chromosome that is derived from an animal cell can be

transferred into a plant cell and be operable as claimed in the instant application, citing Hadlaczsky, 1980).

Applicant's traversal has been considered and is unpersuasive because the cited reference makes no mention of satellite DNA or of artificial chromosomes or of satellite artificial chromosomes.

24. Applicant traverses, stating primarily that (Response p. 41) the issue of whether the specific instant claims are enabled by the specification should not turn on the state of the art regarding the similarities between plant and animal chromosomal composition and function, as discussed on pages 5-8 of the Office Action. Applicant asserts that the relevant question with regard to enablement of the subject matter of the instant claims is whether the particular steps and materials of the claimed methods are described in the specification in such a way as to enable one skilled in the art to make and use the subject matter as claimed. Therefore, the instantly claimed methods are described in detail in the application to the satisfaction of 35 USC 112, first paragraph.

Applicant's traversal has been considered and is unpersuasive because the state of the art must be considered to determine enablement because the scope of the claims is not limited to an animal. Rather the scope of the claims encompasses plants and plant cells. The specification sets forth no working examples of plant satellite artificial chromosome. Because the scope of the claims encompass both animal and plant satellite artificial chromosomes, the state of the art at the time the invention was made must be considered to determine whether the full scope of what is claimed is enabled. As previously stated in the Office Action, plant and animal satellite DNAs different, and

therefore it is predicted that the plant satellite artificial chromosome will differ from the animal satellite artificial chromosome. Plant DNA is generally more GC-rich than animal DNA. Plants and animals have different requirements for gene expression. Plants have cell walls and animals do not. Plants are auxotrophs and animals are heterotrophs. Since Applicant provides no guidance in addressing these differences, then the Applicant is not enabled for the claimed invention as commensurate in scope with the claims.

The Declaration of Fabijanski

The Declaration of Fabijanski has been thoroughly considered and is found not to be commensurate in scope with the scope of the claims.

25. Applicant traverses, stating primarily (response, p.18) that the Declaration of Fabijanski (declaration p. 2) states that "using methods and materials described in the..application and standard methods described therein", he and other project scientists have demonstrated that SATAC can be transferred to plant protoplasts, using microcell-mediated fusion of SATAC containing murine (mouse) cells with plant protoplasts, and lipid-mediated transfection of isolated SATAC into plant protoplasts. The Declaration further states that SATAC were introduced into tobacco using microcells prepared from murine cells containing a SATAC as described in US patent No 6,077,697, issued 20 June 2000.

Applicant's traversal has been considered and is unpersuasive because the disclosure must be complete as of the date of filing. US patent No 6,077,697, issued 20 June 2000, is a post-filing date reference.

26. Applicant traverses, stating primarily that the Fabijanski Declaration states (Declaration, pages 2-5) that the following experiments have been done by him: (a) the transfer of a mouse SATAC into tobacco cells using microcell-mediated fusion, (b) the transfer of a mouse SATAC into Arabidopsis cells using microcell-mediated fusion, and (c) the transfer of a mouse SATAC into rice protoplasts (using protocols of US 6,077,697) using lipid-mediated transfection. Applicant concludes that SATACs can be transferred to plant cells.

Applicant's traversal has been considered and is unpersuasive because the Declaration is lacking any teaching of a plant SATAC, a plant SATAC in a plant cell, a plant SATAC in a plant, or a plant SATAC in an animal cell.

27. The Declaration of Fabijanski fails to provide any identifiable components of a SATAC , including a plant SATAC as claimed. Even after consideration of the Declaration, one would not be reasonably apprised of what components make up a SATAC, or a plant SATAC.

Remarks

28. No claim is allowed.

29. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Georgia L. Helmer whose telephone number is 703-308-7023. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on 703-306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Georgia Helmer PhD
Patent Examiner
Art Unit 1638
October 20, 2003

PHUONG T. BUI
PRIMARY EXAMINER
10/20/03